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<p>(21) International Application Number: PCT/SE83/00439 (22) International Filing Date: 15 November 1983 (15.11.83)</p> <p>(31) Priority Application Number: 8206533-5 (32) Priority Date: 17 November 1982 (17.11.82) (33) Priority Country: SE</p> <p>(71)(72) Applicant and Inventor: SWANBECK, Gunnar [SE/SE]; Trollåvägen 29, S-436 00 Askim (SE). (74) Agents: ROTH, Michel et al.; Göteborgs Patentbyrå AB, Box 5005, S-402 21 Göteborg (SE).</p> <p>(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), DK, FI, FR (European patent), GB (European patent), JP, LU (European patent), NL (European patent), NO, SE (European patent), US.</p>		Published <i>With international search report. With amended claims.</i>	
<p>(54) Title: A DEVICE FOR RINSING AND TREATING WOUNDS AND INFECTED SKIN PORTIONS</p> <p>(57) Abstract</p> <p>A device for rinsing and treating wounds and infected skin portions and comprising a suction cup (10) which is placed over the area to be treated and a vessel (15) for a treatment solution, said vessel by way of a tube connection (11, 12) communicating with the interior of the suction cup. The treatment solution is intended to fill up at least a substantial part of the volume of the suction cup (10). The vessel (15) and suction cup form by way of the tube connection a closed liquid system for the treatment solution. A pump (13) may be arranged to cause the solution to circulate between the suction cup (10) and the vessel (15). A suction effect is created within the cup (10) by keeping this on a level above the vessel (15).</p>			

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A device for rinsing and treating wounds and infected skin portions

Technical field

The present invention refers to a device for rinsing and treating wounds and infected skin portions and comprising a cup-shaped member covering the area to be treated and having its opening towards this, said device further comprising a vessel for a treatment solution, said vessel by way of a tube connection communicates with the interior of the cup-shaped member, at which the treatment solution is intended to fill up at least a substantial part of the volume of the cup-shaped member and forming a liquid surface against the area to be treated for exchanging components between this and the treatment solution, and wherein the interior of the cup-shaped member is arranged to be kept at a lower pressure than the atmospheric pressure.

Background of the invention

The conventional method for treating chronic and infected wounds, such as bedsores, leg ulcers etc. is manual washing and moist compresses soaked with a common salt solution and if necessary enzymes for promoting the healing process. In recent years a new medical preparation called Debrisan ^R consisting of small, dry, porous beads has been used to a limited extent and is declared to have a better absorption capacity as compared to most common salt compresses.

Devices for rinsing and treating wounds have also been proposed, in which a cup with its opening facing the wound is applied about the wound area, said cup having an inlet and an outlet opening and a liquid is caused to pass through the cup. Said liquid can contain antibiotics and substances which improves the healing process. Bacteria and waste products from



the wound are washed away with the cleansing solution. Such a device is shown in DE-OS 2,809,828 and US patent No. 2,280,915. Since often long treatment periods are required for obtaining a desired result large volumes of cleansing solution are consumed, which means great expenses especially if the solution contains substances as antibiotics, enzyme preparations, vitamins etc.

The purpose and most important features of the invention

The object of the present invention is to provide a device of the kind mentioned in the introduction, which makes it possible to treat wounds and infected skin portions in an economically justified way even during long periods of time and which improves the healing of the wound and besides in certain cases can compensate for an insufficient blood-circulation, e.g. in leg ulcers.

This has been achieved by the fact that said vessel and cup-shaped member by way of said tube connection form a closed liquid system thereby providing a uniform low pressure within the cup-shaped member, which may be regulated by the level difference between the cup-shaped member and the vessel.

Description of the drawings

The invention will now be further described with reference to the accompanying drawings, where Fig. 1 and 2 schematically show two different embodiments of the invention.

Description of the embodiments

The device according to Fig 1 comprises a suction cup 10 of rubber, plastic or glass and which has an inlet and an outlet opening, to which a feed and a discharge tube 11 and 12 resp. are connected. The discharge tube 12 leads by way of a pump 13 and a sterilizing filter 14 down into a bottle 15 containing a treatment solution. The pump 13 is preferably a so called



peristaltic pump. The tube 11 connected to the inlet opening of the suction cup 10 leads from the bottle 15. The interior of the bottle 15 is kept at atmospheric pressure by means of an air tube 16. Oxygen may also be bubbled into the solution by way of a tube 17 to ensure oxygenation of the wound to be treated. The suction cup is applied over the wound area or the infected skin portions to be treated. The solution is caused to circulate through the system and is prevented from leaking out from the suction cup 10 by applying a pressure to the cup. This pressure may be created by an external bandage or by having a somewhat lower pressure inside the cup than in the surrounding atmosphere. This lower pressure may be regulated by the level difference between the bottle and the suction cup. i.e. the hydrostatic pressure difference. It can also be regulated by the flow resistance between the bottle and the suction cup and by the speed of flow. The pressure can also be regulated by a separate pressure regulator.

The low pressure in the suction cup provides besides preventing leaking from the suction cup, that interstitial fluid is sucked out from the wound and facilitates that blood components are transported to the wound and that microorganisms are easier washed away from the wound.

The suction cup may be of different sizes, shapes and materials, such as glass, rubber or plastic etc. The suction cup has an opening towards the skin area to be treated and inlet and outlet openings for the solution. The size of the opening towards the skin may vary from some mm² to some dm². The volume of the solution may vary from some ml to several liters.

The sterilizing filter 14 which may either be placed between the pump 13 and the bottle 15 or between the suction cup 10 and the pump can have a porosity of about 0.22 micron, to filter out all bacteria, up to about 0.80 micron to get a good degree of cleaning of the solution. The sterilizing filter 14 is however in most cases unnecessary and can thus be



eliminated.

The bottle 15 with the treatment solution may be placed in a thermostatically regulated water bath to ensure a certain temperature of the treatment solution.

The active ingredients in the solution to be circulated may be a cleaning agent, compounds for nutrition of the tissue including oxygen, vitamins, amino acids and glucose, drugs of different types such as antibiotics, antiinflammatory agents, e.g. cortison, and enzymes for digestion of necrotic tissue, coagulum and pus.

The solution may be of the types used for intravenous infusion or for skin cleaning. It is however possible that a better result may be obtained with new developed solutions for this special purpose.

The circulation of the solution enables a larger volume of the solution and by that a greater amount of nutritives, drugs etc. to come in contact with the wound to be treated and to get a continuous sterilization of the solution if the sterilizing filter 14 is used. The circulation will also give an effective cleaning of the wound as the solution all the time will be flowing over the wound and wash away waste products therefrom. As was mentioned above a continuous oxygenation of the wound may easily be obtained by bubbling oxygen into the treatment solution in the bottle.

Especially at chronic leg ulcers the device according to this invention may be regarded as a substitute for the insufficient blood circulation in the ulcer area.

If a continuous treatment is desired during a long period of time the filter 14 and the treatment solution may be exchanged e.g. by arranging a T-connection with a valve between the bottle 15 and the suction cup 10 and between the pump 13 and the filter 14.



In the embodiment shown in Fig. 2 the pump is eliminated and the cup 10 is connected to the bottle 15 only by way of the tube 11. The outlet opening 10 of the cup is closable. The solution is caused to raise into the cup 10 through the tube 11 by raising the bottle 15 to a higher level, at which the outlet opening of the cup is open. When the solution starts flowing out through said opening this is closed by a stopper 18 or the like, after which the bottle is lowered to a level below the cup 10. The interior of the cup will then have a negative pressure corresponding to the level difference to the bottle. A certain natural circulation caused by convection will take place within the cup, at which there will be an exchange of components between the wound and the treatment solution.

In practice it may be appropriate to start a treatment with the device according to Fig. 1 and when the healing process has advanced change to the device according to Fig. 2.

The most important fields of application for the device according to the invention are:

1. Cleaning of chronic and infected ulcers such as pressure ulcers, leg ulcers etc.
2. Substituting and complementing the blood circulation in arterial- or venous insufficiency of the legs in leg ulcer patients.
3. Administration of drugs such as antibiotics and antiinflammatory compounds in a controlled and exact way in for instance vasculitis ulcers.
4. Treatment of superficial skin infections, such as impetigo, herpes simplex and mycoses. Clinical tests have been performed with the device according to Fig. 1 and the results thereof will be given below.



Clinical tests

The patients have been treated for approximately two hours daily till the lesions have healed. If pain was felt due to the low pressure the treatment was stopped when the patient so wanted. In one of the patients the treatment was stopped after 45 minutes the first week of treatment. Subsequently the patient could stand treatment for two hours daily. Two patients with leg ulcers due to an established arterial insufficiency, two patients with ulcers due to venous insufficiency, one patient with a diabetic ulcer and one patient with pyoderma gangrenosum have taken part in the preliminary clinical trial. One of the patients with arterial insufficiency had two ulcers that were treated, not simultaneously but in succession.

Case 1. 93-year old woman that after childbirth got problems with varicous veins and subsequently had several deep vein thromboses. Since the age of 80 she suffered from recurrent leg ulcers. Some months before treatment started with external circulation she got several ulcerations on both legs. Oscillometry and systolic ankle and toe pressure gave values indicating threatening gangraene. Treatment with external circulation gave complete epithelialization in nine weeks.

Case 2. 73-year old man who earlier had vein thromboses three times in his left leg. The first leg ulcer came in 1968 and has recurred since then in both legs but mostly in his left leg. In 1980 he was considered having a combined arterial and venous insufficiency causing his leg ulcerations. He was operated for insufficient perforating veins in his left leg the same year. After the operating the surgical wound did not heal. The patient also developed some other ulcerations on the same leg. First we started treating the initial three year old surgical wound with external circulation. After nine weeks when this ulcer was healed, we went on with treating another wound distal and lateral to the surgical wound. After seven



weeks of treatment the wound was epithelialized over 80 percent of its surface.

Case 3. 65-year old woman with diabetes and hypertension. She had a small traumatic ulceration on the ventral side of the left leg in 1948. The ulceration has recurred several times but since 1978 it had not healed in spite of several types of treatment including reconstructive surgery. In 1982 toe pressure in the first left toe was 30 mmHG indicating arterial insufficiency. After eight weeks of treatment with external circulation the ulcer was healed.

Case 4. 57-year old woman with mild hypertension who had vein thrombosis in her left leg in 1957 and 1973. The patient had a 1.5x2 centimeter ulcer for half a year over the left medial malleolus when treatment with external circulation was started. After three weeks of treatment the ulceration was healed.

Case 5. 63-year old man with recurrent leg ulcerations since 1976. He had no sign of arterial insufficiency. In August 1982 he got a 1 centimeter ulceration on the medial side of his left leg. In February 1983 he got another 1 centimeter ulcer close to the former. Both ulcers were treated simultaneously with external circulation and both were healed in three weeks.

Case 6. 27-year old woman with pyoderma gengrenosum since 1972. The ulceration have mainly appeared on her legs and arms. For the last 18 months she had had ulcerations all the time and refused taking prednisolon. One of her fresh ulcers had a diameter slightly over 1.5 centimeter. After three weeks of treatment the ulcer was healed.

Results

Daily treatment with external circulation of a nutrient solution under low pressure has been effective in healing the seven ulcerations of the six patients. For the three patients



without arterial insufficiency the healing rate has been considerably shorter than for those with arterial insufficiency on the basis of arteriosclerosis or diabetes mellitus.

When the daily treatment was stopped there was an oedema under the treatment cup. The oedema disappeared within a few hours. Pain was recorded for one patient after the low pressure had been applied. for about 45 minutes. After a few weeks of treatment the pain did not appear.

For two patients albumin determination in the circulating nutrient fluid after two hours of treatment was performed. Values corresponding to about 0.5 ml of serum was obtained.

For the patients with arterial insufficiency including the diabetic patient the ulcers healed first with an epithelialization and later on after the treatment had been stopped the dermal defect was filled out. Epithelialization thus seemed to proceed granulation under the conditions of this type of treatment.

The invention is of course not limited to the embodiments shown in the drawings but can be notified within the scope of the claims.



Claims

1. A device for rinsing and treating wounds and infected skin portions and comprising a cup-shaped member (10) covering the area to be treated and having its opening towards this, said device further comprising a vessel (15) for a treatment solution, said vessel by way of a tube connection communicates with the interior of the cup-shaped member, at which the treatment solution is intended to fill up at least a substantial part of the volume of the cup-shaped member and forming a liquid surface against the area to be treated for exchanging components between this and the treatment solution, and wherein the interior of the cup-shaped member (10) is arranged to be kept at a lower pressure than the atmospheric pressure.

characterized in,

that said vessel (15) and cup-shaped member (10) by way of said tube connection (11,12) form a closed liquid system, thereby providing a uniform low pressure within the cup-shaped member, which may be regulated by the level difference between the cup-shaped member and the vessel (15).

2. A device according to claim 1.

characterized in,

that a tube connection (11) is arranged between the vessel (15) and an inlet opening in the cup-shaped member (10) and a second tube connection (12) is arranged between an outlet opening in the cup-shaped member and the vessel, and that a pump (13) is provided at said second tube connection for causing the treatment solution to circulate between the cup-shaped member and the vessel.

3. A device according to claim 2.

characterized in,

that a sterilizing filter (14) is arranged between said outlet opening and the vessel (15).



4. A device according to claim 1,

characterized in,

that the vessel (15) by way of a tube connection (11) is connected to an opening in the cup-shaped member (10), which has a second closable opening and that in use of the device the tube and at least a substantial part of the cup-shaped member are filled with treatment solution and said second opening is closed, at which the low pressure in the cup-shaped member is maintained and can be regulated by the level difference between the cup-shaped member and the vessel.



AMENDED CLAIMS

[received by the International Bureau on 24 April 1984 (24.04.84);
original claims 1 to 4 replaced by claims 1 and 2]

1. A device for rinsing and treating wounds and infected skin portions and comprising a cup-shaped member (10) covering the area to be treated and having its opening towards this and said member having inlet- and outlet openings, said device further comprising a vessel (15) for a treatment solution intended to pass through the cup-shaped member and fill up at least a substantial part of the volume thereof and forming a liquid surface against the area to be treated for exchanging components between this and the treatment solution, and wherein the interior of the cup-shaped member (10) is arranged to be kept at a lower pressure than the atmospheric pressure,

characterized in,

that said vessel (15) by way of said tubes (11, 12) is connected to both the inlet- and outlet openings of the cup-shaped member (10), so that a closed liquid system is formed between said member and said vessel, and that a pump (13) is provided between said outlet opening and the vessel for causing the treatment solution to circulate in said liquid system.

2. A device according to claim 1,

characterized in,

that a sterilizing filter (14) is arranged between said outlet opening and the vessel (15).



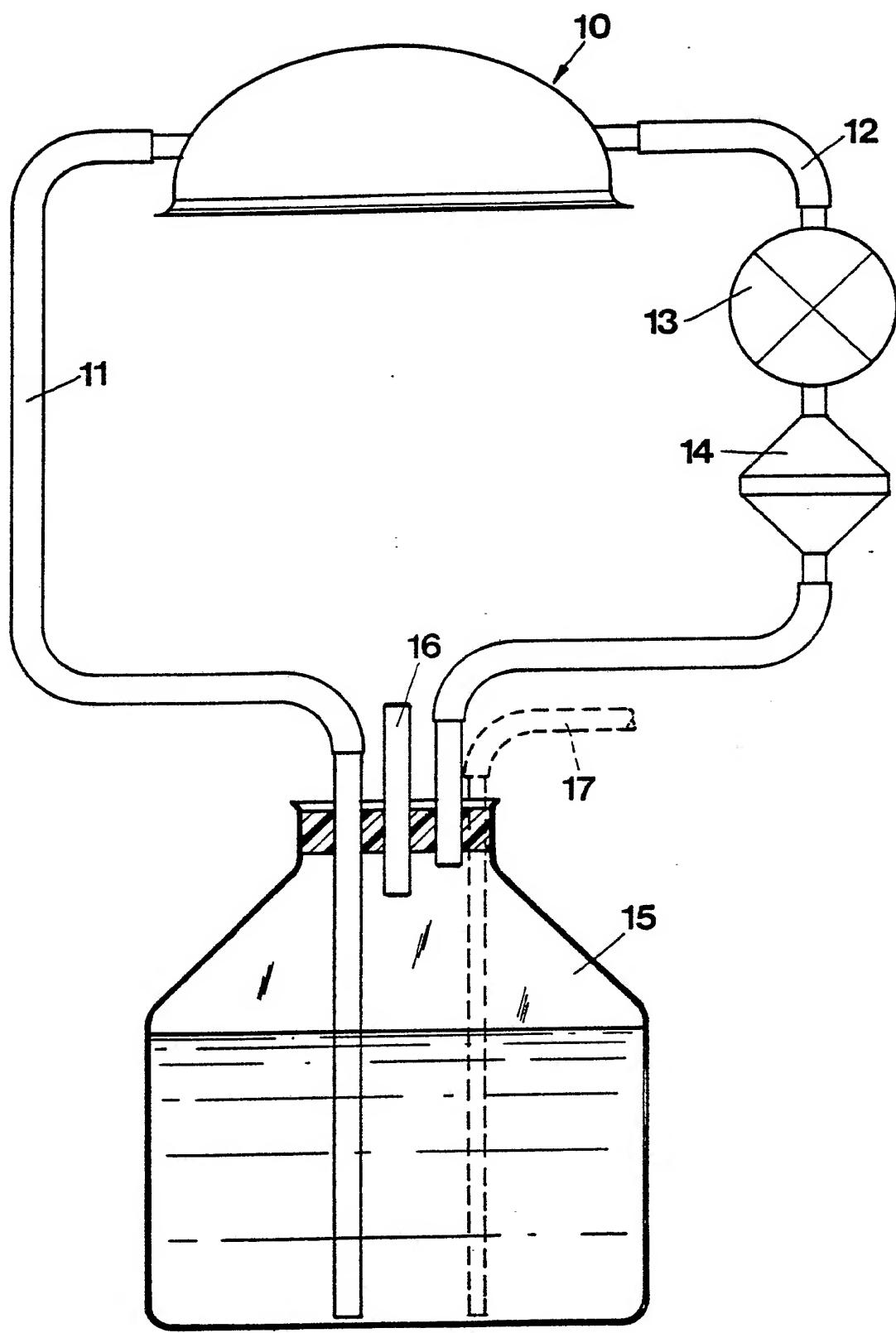
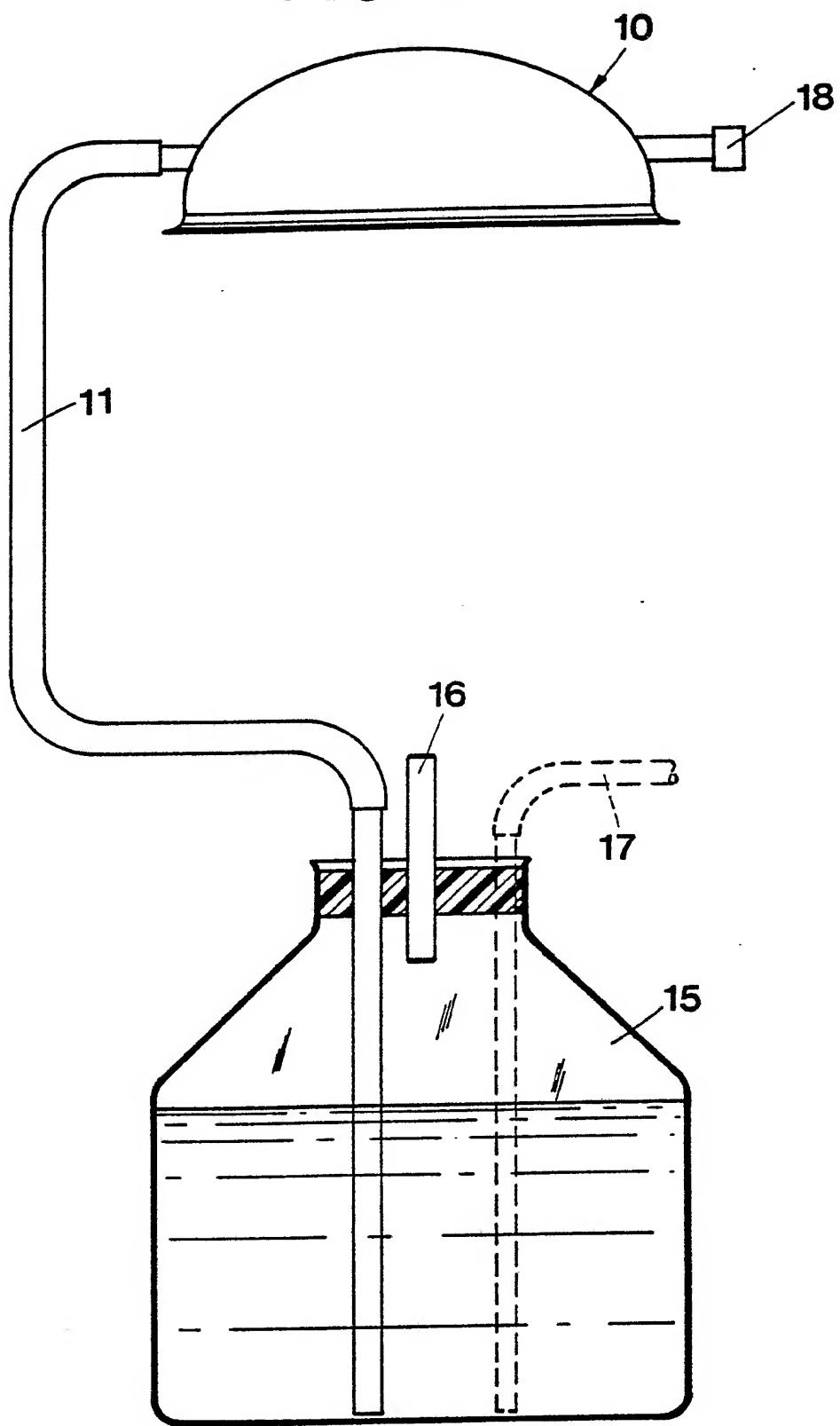
FIG 1

FIG 2

INTERNATIONAL SEARCH REPORT

International Application No PCT/SE83/00439

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ³

According to International Patent Classification (IPC) or to both National Classification and IPC 3

A 61 M 35/00

II. FIELDS SEARCHED

Minimum Documentation Searched ⁴

Classification System	Classification Symbols
IPC 3	A 61 F 13/00, A 61 H 33/00, 35/00, A 61 M 35/00, 37/00
US CL	<u>128:114, 260, 268, 269, 273</u>

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched ⁵

SE, NO, DK, FI classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴

Category ⁶	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
Y	SE, B, 402 212 (GAMBRO AB)	1
X	26 June 1978	2
&	DE 2745347	
	JP 53048979	
	US 4191646	
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X		2
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	12 June 1980	
&	GB 2047543	
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X	GB, A, 641 061 (J D MAC LAURIN)	4
	2 August 1950	
Y	US, A, 2 280 915 (J H JOHNSON)	1
	28 April 1942	
X	US, A, 3 026 874 (R C STEVENS)	4
	27 March 1962	

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IV. CERTIFICATION

Date of the Actual Completion of the International Search ⁹

1984-02-16

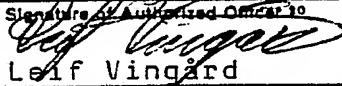
Date of Mailing of this International Search Report ⁸

1984-02-23

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Signature of Authorized Officer ¹⁰


Leif Vingård